we have some devices that are already OTC. That is an irreversible --

DR. RUNNER: But not intraoral appliances.

CHAIRPERSON GULYA: Right, right. But we're kind of mixing a little bit apples and oranges.

DR. ORLOFF: Lisa Orloff. A huge component of the prescription aspect of it is baseline exam by the health care professional, which not only documents whether the patient has cardiovascular disease, malocclusion to begin with, other pathology, but you know what their baseline is. So you can collect the follow-up data and know what kind of change has occurred.

CHAIRPERSON GULYA: All right. Yes, Ms. Howe?

MS. HOWE: Betsy Howe. I hope we're not closing the door on the possibility of receiving information on a study based on all the criteria that we have just talked about, that perhaps there is a product that is going to be developed on the marketplace that could serve consumers. I hope we have just recorded the kinds of studies and data

collection that would be required.

CHAIRPERSON GULYA: Okay. Dr. Calhoun?

DR. CALHOUN: Karen Calhoun. I don't think anyone is closing the door on that. On the other hand, we want to be sure that if something is marketed to the consumer as efficacious for the treatment or snoring or obstructive sleep apnea, that we're convinced it really is efficacious. And for that, we need more data other than handing something out in a shopping mall and asking the consumer, "Did this help your snoring?"

CHAIRPERSON GULYA: Dr. Woodson?

DR. WOODSON: Yes, Dr. Woodson. The other issue, I think one of the major holdbacks that all of us feel about marketing something for sleep apnea is we're talking about endpoints.

How is the patient going to know if it's effective if he doesn't have a sleep study, you know, if he's using it? And that's one of the patient doesn't know if I'm mild, moderate, or severe. He doesn't know if he even has it. So that's why we're so reluctant to approve over-the-counter indications

of any treatment for sleep apnea.

CHAIRPERSON GULYA: In terms of snoring, though, there might be?

DR. WOODSON: Yes.

CHAIRPERSON GULYA: But that was kind of why I went through the exercise of the discussion so that FDA had a feeling for what our thoughts were in terms of study design and so on. So there was some foundation and discussion for eventually perhaps that type of thing happening.

All right. Any specific device types or indications which would not require clinical data? My hunch is that the mandibular reposition device is not going to fall into this category. Would it be safe to say that none of the oral appliances would fall into this?

(No response.)

CHAIRPERSON GULYA: Okay. Great. So, therefore, we are going to things like that are already OTC; am I correct, nasal dilators and cervical pillows? Any difference of opinion with that? Do I hear any thoughts?

DR. TERRIS: David Terris. "Not require clinical data." I'm not sure I understand what they're asking.

DR. MAIR: Something you can do bench work on without requiring a clinical trial that you can have something approved.

DR. TERRIS: That's it? So bench work?

CHAIRPERSON GULYA: I was kind of assuming that they could just submit their --

DR. MAIR: Or computer simulations or whatever, no data or no --

EXECUTIVE SECRETARY S. THORNTON: Dr. Mann, perhaps you could come to the podium and clarify that for the panel.

DR. MANN: It was basically a general question that was brought up during formulating questions. We didn't have any particular device type in mind, but depending on how the discussion went during the panel meeting, we wanted to just leave the door open if there was any situation a particular device which the panel thought might be appropriate for that kind of thing.

CHAIRPERSON GULYA: What do you mean by "clinical data"? I was under the assumption that if a manufacturer came with device X, that it was a device that you really didn't need to see any reduction in snoring or you didn't need any clinical data for. Is this what you're asking?

DR. MANN: Yes, but when we're talking about clinical data, we're talking about measurement of symptoms, subjective improvement, those sorts of things, versus just a type of study which would look at descriptive characteristics, bench performance-type data, and so forth.

CHAIRPERSON GULYA: I see. Okay. All right. Do we see any of these devices that --

DR. ROSENTHAL: May I just make a comment?

CHAIRPERSON GULYA: Sure. Dr. Rosenthal?

DR. ROSENTHAL: In the 510(k) realm, which is a much more complicated issues than PMAs, which you are used to dealing with, the companies have to show substantial equivalence.

Now, if you got a little piece of Band-Aid and you could show it was substantially equivalent to

the previous little piece of Band-Aid, we need to know whether or not you would feel that that would have to be propped up by clinical observations as well as just by the inherent characteristics of the Band-Aid. That's I think what Eric was getting at.

I mean, for example, in the eye world, the glaucoma valves, they have to do clinical studies on them, whether they're identical to previous glaucoma valves or not. In this world we would like your opinion on whether or not you would like to see the clinical data, regardless of what the basic configuration of the device was.

CHAIRPERSON GULYA: Okay. Thank you.

Dr. Terris, I see you going to the mike here.

DR. TERRIS: Just a brief comment. There was a concern raised about closing the door on studies if we say we're not going to accept this data. I think one of the reasons we were asked to come up with endpoints and adverse outcomes and so forth to look at is to advise companies that are interested in bringing something to market to say, "Hey, this is what you

need to do to get it passed."

And so that's my concern, communicating eloquently these studies that it doesn't -- you know, from my perspective, it doesn't matter if it's efficacious because of my concern about missing the opportunity to diagnose patients.

So that's my only reluctance to communicate that to the companies that may spend a lot of money trying to get something to market when, in fact, many of us would not approve it anyway because of the absence of diagnosing their sleep apnea.

MEMBER JENKINS: Jenkins. Your question, it seems that to prove that it's equivalent, they would have to show that clinically it's equivalent, not just other characteristics.

DR. ROSENTHAL: That's not always the case, Dr. Jenkins. In many areas in the device world, they can show substantial equivalence by other means other than clinical equivalence.

MEMBER JENKINS: Without clinical data?

DR. ROSENTHAL: Correct.

DR. ORLOFF: Lisa Orloff.

CHAIRPERSON GULYA: Dr. Orloff?

DR. ORLOFF: Within the categories of devices that we're discussing, I think one of the drawbacks of the nasal dilators is that the Breathe Right Strips, which you might be able to imagine you could potentially compare something that's substantially equivalent.

The risk is very low, but it's grouped in with devices that go within the nose and do have more potential for mucosal damage for getting lost in the nose. So since they're all in that same category, I think it would require clinical data to approve them.

CHAIRPERSON GULYA: Okay. Thank you.

Anybody else have any other thoughts here?

MR. CROMPTON: Mike Crompton. I think there's an abundance of guidance from FDA and would hope the panel would not throw all nasal dilators into one category. FDA does look at the device, allows the sponsors to select devices that are substantially equivalent.

I would echo Dr. Rosenthal that many substantial equivalence arguments are not based on

clinical data. They're based on design controls, bench testing, things like that.

And I don't think that the nasal strip would go with the insertion device. Most sponsors wouldn't do that.

CHAIRPERSON GULYA: Right. Yes, Dr. Woodson?

DR. WOODSON: Yes. I think since some of us had such surprise that the nasal strip really was efficacious, I think we would like to see the efficacy data for the substantially equivalent strips.

CHAIRPERSON GULYA: Okay. Yes, Dr. Mair?

DR. MAIR: I have a question for the FDA folks. Once a device is cleared for over-the-counter, whether it be in this case for snoring or mild sleep apnea, is there a process for review of the literature to make sure that with subsequent data that has been developed in clinical trials, et cetera, that it still should be approved? In other words, is the literature updated and reviewed or once it's approved, go for it?

DR. RUNNER: Pretty much once the device is approved, it is going to be out there. The way we

would change any decision that would be made would be on adverse event data that is collected. And that's through our MDR report and MedWatch, et cetera. And given a significant amount of adverse event report data that comes into the agency, we can re-look at a device or a design or labeling related to the device.

DR. MAIR: Eric Mair. So we look at safety and efficacy to pass a PMA. To re-look at it again, we only look at safety? So, in other words, if studies come out showing the efficacy is no longer there, is that --

DR. RUNNER: You're talking about PMA versus 510(k). I mean, they're a little bit different in terms of how they're looked at. PMA is more strictly held in terms of that, but it's primarily safety, you know, safety problems.

DR. MAIR: I guess what I am getting at specifically is clinical pillows for OSA. I'll go right to it. I'll play my cards down. It's something that has been approved for OTR for mild obstructive sleep apnea. If the data, the newer data, coming out is saying that this is not acceptable for obstructive

sleep apnea, is it still approved over the counter, not a safety concern but just efficacy?

DR. ROSENTHAL: You forget, Dr. Mair, that it's the company --

DR. MAIR: I forget a lot.

DR. ROSENTHAL: -- who submits the data to us. Now, if the company is going to come in and submit new data from the literature and ask to change their indication, we would have to consider it.

DR. MAIR: What I'm asking for is not what the company submits. It's already been accepted for OTR for mild OSA. Now there are other studies that are coming out.

DR. ROSENTHAL: We generally let the clinical community make those decisions. I mean, it's just like a PMA. I'm sure you know of devices that have been approved under PMA that are no longer being used because the clinical trial may have, in fact, shown something that was efficacious and is relatively safe but when out in the clinical community, people don't find it very useful at all.

CHAIRPERSON GULYA: Yes, Dr. Calhoun?

DR. CALHOUN: But if it's OTC, the effect of the relatively sophisticated opinion of the medical community probably has very little impact, if any.

DR. MAIR: It's whoever advertises better, --

DR. ROSENTHAL: Right. Well --

DR. MAIR: -- which is scary.

DR. ROSENTHAL: But it's scary with all OTC products, frankly.

CHAIRPERSON GULYA: Right. I think that, again, we can't turn back the wheel of time here. So I think -- let me check with the FDA once again -- that we have covered all of the issues for them, that they -- I see a nodding there, that we have answered all of their questions.

We have given them something to chew on in terms of potential clinical data that would be useful for somebody to propose one of these devices for OTC use, although we must all emphasize that the overwhelming majority of the panel believed that the oral appliances were not appropriate for over-the-counter use as far as we can determine.

Well, we now have just about enough time for a break. And then we will go into the second open hearing session. Any announcements?

EXECUTIVE SECRETARY S. THORNTON: Not at this time.

CHAIRPERSON GULYA: Okay. All right. So let's see. Let's take about a 15-minute break and be back here at 3:30.

(Whereupon, the foregoing matter went off the record at 3:18 p.m. and went back on the record at 3:41 p.m.)

SECOND OPEN PUBLIC HEARING SESSION

CHAIRPERSON GULYA: We will now call to order the second open public hearing session. Again, as before, this is the opportunity for the members of the public who have an interest in addressing the panel on today's topic. And for those of you who are new to the session here, we are talking about over-the-counter versus prescription use of devices for snoring and obstructive sleep apnea.

As before, each presenter should state clearly for the record their name; affiliation;

interest in the topic at hand; any consulting arrangements or financial interests with medical device firms; and if medical expenses have been paid, by whom.

Yes. And I have to read this. I guess this is going to be a little bit redundant. My apologies.

EXECUTIVE SECRETARY S. THORNTON: No, you don't.

CHAIRPERSON GULYA: I don't have to read this again -- oh, thank you -- which is basically going through again the medical expenses issue.

Now, as I understand it, we have one presenter, Mr. Edward Grandi, one who is registered. And although we have 30 minutes in this session, in fairness for the individuals who had to adhere to a 5-minute time period in the morning session, it would be greatly appreciated if you could do the same. And we have a little device here that will kind of keep us both honest. So if you could proceed, please?

MR. GRANDI: Yes. Thank you. My name is Edward Grandi. I'm the Executive Director of the

American Sleep Apnea Association, Washington, D.C. a national patient interest organization dedicated to educating the general public and the medical community on the diagnosis and treatment of sleep apnea. We are also committed to supporting people in treatment through a network of support groups around the country.

I am interested in this topic because our organization is dedicated to the issue of sleep apnea. I have no financial interest. And I paid my own expenses to get here.

We appreciate the opportunity to comment on the joint meeting of the FDA Dental Products and Ear, Nose, and Throat Device Panels. From all of the things that I have heard during the course of the day, I have no quibbles with anything that anybody has said.

Certainly I think taking a more cautious approach with regard to taking devices that are currently prescribed devices and making them over-the-counter devices is very prudent. I don't think that anybody benefits by having devices that are

available that could possibly injure people by making them more generally available.

So to that extent, I would encourage use of very strict clinical data in looking at new devices. Perhaps if the mandibular devices that currently have not been considered, if they do come up for consideration, that strict standards would be applied in terms of their use.

I would also encourage the use of screening devices, either questionnaires or other types of devices, for people who have snoring and perhaps are not sure whether they have sleep apnea or not, encourage them, as suggested by Ms. Howe, either to visit our Web site or to visit the other Web sites that are available that provide access to questionnaires and devices and other means for determining whether they're at risk of sleep apnea and if they are at risk of sleep apnea, encourage them to visit a medical doctor who can help them get a diagnosis.

I will close by saying that access to sleep studies is an issue. Last week Medicare was

considering the question of portable home studies. I was present at that meeting as well. Certainly by raising awareness of sleep apnea, we are also increasing the need for access to diagnosis and then ultimately to affordable treatment.

I would hope that affordable treatment is not done at the expense of a population who is already suffering a great deal. Thank you for this opportunity to speak.

CHAIRPERSON GULYA: Okay. Thank you, Mr. Grandi.

Is there anybody else out there who wishes to take this opportunity to address the panel? Sally?

EXECUTIVE SECRETARY S. THORNTON: Just for the record, I wanted to make a note of the fact that there were two people who had registered to speak but, unfortunately, were unable to come here to present in person. And their comments have been made available to the panel and to the transcriber. So they will appear in the record. Those people are Barry Krakow, M.D., Medical Director of Sleep and Human Health Institute and the Maimonides Sleep Arts & Sciences

Center. The other person is Alan Barnes, social worker, who is president of an organization called Coaching for Service.

Thank you.

CHAIRPERSON GULYA: Any other comments or questions from our FDA colleagues? Sally? Anybody?

(No response.)

CHAIRPERSON GULYA: Okay. Well, then I would like to thank all the panel members for the hard work they have put into preparing for this meeting. It definitely showed in the discussions. We had some pretty broad-ranging and I think still entertaining and informative discussions as well.

I also would like to thank the FDA staff for all the work they did, particularly Sally and always coaching me here at my right arm, for their presentations and for putting together the workbook as nicely as they did. It was certainly very helpful for me to read these background materials. So it is much appreciated.

I would like to thank the FDA very much for the opportunity I have had to serve as chair of

this panel. It has been a wonderful experience. Hopefully it has been helpful for everybody. It certainly has been something I have enjoyed and look forward to. Thank you very much.

Unless I am missing anything, I think we can adjourn this meeting. We are adjourned.

(Whereupon, at 3:49 p.m., the foregoing matter was adjourned.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: Joint Meeting of the Dental Products and Ear, Nose and Throat Devices Panels (Open Session)

Before: DHHS/PHS/FDA/CDRH

Date: October 6, 2004

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.